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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.    | CONFIRMATION NO. |
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| 10/612,491      | 07/01/2003  | Vahid Saadat         | USGI-004C (31150-1140) | 3557             |

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EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE  | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS                               | 04/17/2007 | PAPER         |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/612,491

Applicant(s)

SAADAT ET AL.

Examiner

Diane Yabut

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7, 9, 16, 26, 27 and 32-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 16, 26, 27 and 32-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

This action is in response to applicant's amendment received on 20 February 2007.

The examiner acknowledges the changes made to the specification and the claims.

#### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 3-7, 9, 26-27, and 32-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Koike et al.** (U.S. Patent No. **6,056,760**) in view of **Gannoe et al.** (U.S. Patent No. **6,746,460**) and **Laufer et al.** (U.S. Pub. No. **20040194790**).

Claims 1, 6, 7, and 38: Koike et al. discloses providing a delivery catheter **1** having a needle **2**, or piercing element, translatably disposed therein, a distal end, one or more anchors **4** disposed within the needle, and sutures  $T_1$  and  $T_2$  coupled to the anchors, advancing the delivery catheter and needle through the a first tissue wall and then through a second tissue wall, and ejecting a first anchor from a distal tip of the needle on a first side of the first tissue wall and ejecting a second anchor from the needle on a second side of the second tissue wall (Figures 6-10). Koike et al. discloses the claimed device except for a stabilization device disposed at the distal end, engaging the stabilization device to a tissue wall of the gastrointestinal lumen before advancing the

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catheter through the tissue wall, and advancing the delivery catheter and needle into the gastrointestinal lumen, or tract of a patient.

Gannoe et al. teaches delivering the delivery catheter and needle, or tissue piercing element into the gastrointestinal lumen, or tract of a patient in order to reduce the amount of food desired by patients who may be obese (col. 1, lines 12-30 and 52-67). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a tissue piercing element into the gastrointestinal lumen, as taught by Gannoe et al., to Koike et al. in order to aid obese patients in managing the amount of food desired and eaten.

Laufer et al teaches a stabilization device **740** disposed at the distal end, engaging the stabilization device to a tissue wall of the gastrointestinal lumen before advancing the catheter through the tissue wall (Figure 4A and page 3, paragraphs 79 and 83). It would have been obvious to one of ordinary skill in the art to provide a stabilization device that engages with the a GI tissue, as taught by Laufer et al., to Koike et al. since it was known in the art that tissue piercing elements may injure or tear tissue from translating or puncturing, as well as withdrawing, retracting movement if the tissue is not stabilized and a stabilization device may prevent injury to the tissue.

Claims 26, 32, and 35: Koike et al. discloses the claimed device, including withdrawing the piercing element from the catheter through tissue and using a connection element in tying together suture threads  $T_1$  and  $T_2$  and a first and second anchor, said second anchor being connected to said first anchor by a suture (see explanation for Claims 1, 6, 7, and 38 above), except for engaging and pulling a tissue

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wall of the gastrointestinal lumen to create a tissue fold, holding the tissue fold within the patient, moving the first and second anchors on either side of the tissue fold, and maintaining the tissue fold via the anchor and the suture and a connection element.

Gannoe et al. teaches engaging and pulling a tissue wall of the gastrointestinal lumen to create a tissue fold, holding the tissue fold within the patient, moving anchors on either side of the tissue fold, and maintaining the tissue fold via the anchor and the suture and a connection element (Figure 4A). It would have been obvious to one of ordinary skill in the art to provide the step of creating a tissue fold, as taught by Gannoe et al., to Koike et al., since it was known in the art that obesity may be treated by forming folds in the gastrointestinal lumen which aids obese patients in managing the amount of food desired and eaten.

Claim 3: Koike et al. discloses ejecting an anchor from a distal tip of the needle comprising translating a push rod 3 disposed in the needle (Figure 1 and col. 4, lines 58-67).

Claims 4 and 9: Koike et al. and Gannoe et al. disclose the claimed device except for the stabilization device comprising a coil 740, or tissue holding element, having a sharpened tip and engaging the stabilization device to the tissue wall comprising rotating the coil to engage the coil into the tissue wall before advancing the catheter through the first tissue wall. See explanation for Claims 1, 6, 7, and 38.

Claim 5: Koike et al. discloses advancing the needle through the tissue wall further comprising translating the needle distally through the delivery catheter (Figures 6-10).

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Claim 27: Koike et al. discloses the claimed device except for providing a second anchor including a suture coupled thereto and creating a second tissue fold on an opposing tissue wall.

Gannoe et al. teaches providing a second anchor including a suture coupled thereto and creating a second tissue fold on an opposing tissue wall (Figure 5A and col. 5, lines 23-37). It would have been obvious to one of ordinary skill in the art to provide a second tissue fold, as taught by Gannoe et al., to Koike et al. since it was known in the art that multiple folds greatly reduces the area of a gastrointestinal lumen, and again, aids obese patients in managing the amount of food desired and eaten.

Claims 33, 34, 36, and 37: Koike et al. discloses the claimed device except for forming the tissue fold, or bringing the first and second tissue walls adjacent, results in reducing the cross sectional area of a lumen in a patient, as well as the volume of an organ.

Gannoe et al. teaches forming the tissue fold, or bringing the first and second tissue walls adjacent, results in reducing the cross sectional area of a lumen in a patient, as well as the volume of an organ. See explanations for Claims 1, 6, 7, 26, 27, 32, 35, and 38.

9. Claims 2 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Koike et al.** (U.S. Patent No. **6,056,760**), **Gannoe et al.** (U.S. Patent No. **6,746,460**) and **Laufer et al.** (U.S. Pub. No. **20040194790**), as applied to Claims 1 and 6 above, and further in view of **Matsui et al.** (U.S. Patent No. **6,352,503**).

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Claims 2 and 16: Koike et al., Gannoe et al., and Laufer et al. discloses the claimed device except for an imaging element in the vicinity of the distal end of the delivery catheter and using the imaging element to provide visual guidance during engagement of the stabilization device to the tissue wall.

Matsui et al. teaches an imaging element 1 in the vicinity of the distal end of the delivery catheter and using the imaging element to provide visual guidance during engagement of the stabilization device to the tissue wall (col. 5, lines 18-30). Matsui et al. teaches that the use of an endoscope can readily and positively perform treatment on a body cavity of a patient (col. 1, lines 47-51 and col. 2, lines 1-16). It would have been obvious to one of ordinary skill in the art to provide an imaging element, as taught by Matsui et al., to Koike et al., Gannoe et al., and Laufer et al. in order to perform treatment on a body cavity readily and positively perform surgery on a body cavity.

### ***Response to Arguments***

1. Applicant's arguments filed 20 February 2007 have been fully considered but they are not persuasive.
2. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art.

3. The applicant argues that the Koike reference contains no teaching or suggestion to combine its devices and methods with the devices and methods with either Laufer or Gannoe. The examiner disagrees. All references are directed to piercing, engaging, or approximating tissue which one of ordinary skill in the art would recognize are applicable to various locations in the body. Therefore, as maintained above, it would have been obvious to one of ordinary skill in the art to modify Koike with Gannoe and Laufer since it was known in the art that piercing the gastrointestinal lumen is applicable and beneficial in aiding obese patients, as taught by Gannoe, and that a stabilization device would be effective in preventing injury to the tissue, as taught by Laufer.

4. In response to applicant's general argument that the references are incompatible with one another, such as how the Laufer stabilization device would possibly be combinable with the Koike delivery catheter, the test for obviousness is not whether the features of a secondary or tertiary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art.

5. Applicant argues that Gannoe does not teach or suggest using anchors disposed within a tissue piercing element for any purpose and that the examiner ignores the device and method are directed to a space-occupying device to be implanted in the stomach. Gannoe does indeed teach or suggest using anchors disposed (see abstract and paragraph 8 above) within a tissue piercing element, and by anchoring the space-occupying device, Gannoe reads on the limitation of delivering a delivery catheter and



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needle, or tissue piercing element into the gastrointestinal lumen, or tract of a patient in order to reduce the amount of food desired by patients who may be obese. Both Koike and Gannoe involve piercing and engaging tissue, and one of ordinary skill in the art would have looked to Gannoe to modify Koike.

6. Applicant also argues that the Koike patent has nothing to do with “forming folds in the gastrointestinal lumen” or any other methods relating to obesity treatment. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. One would look to Gannoe to modify Koike since both are in the same field of endeavor of piercing, engaging, and approximating tissue.

7. Lastly, applicant argues that Matsui does not provide any teaching or suggestion that would have motivated a person of skill in the art to modify the combined references of Koike, Gannoe, and Laufer. The examiner disagrees. As maintained above, it would have been obvious to one of ordinary skill in the art to provide an imaging element, as taught by Matsui, in order to perform treatment on a body cavity readily and positively perform surgery on a body cavity.

***Conclusion***

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY



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SUPERVISORY PATENT EXAMINER